Citation:

Tucker KL, Hallfrisch J, Qiao N, Muller D, Andres R, Fleg JL; Baltimore Longitudinal Study of Aging. The combination of high fruit and vegetable and low saturated fat intakes is more protective against mortality in aging men than is either alone: the Baltimore Longitudinal Study of Aging. *J Nutr.* 2005 Mar;135(3):556-61.

PubMed ID: 15735093

Study Design:

Prospective Cohort Study

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:



POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine associations between habitual fruit and vegetable intake and saturated fat intake, separately and in combination, and subsequent coronary heart disease and total mortality among men in the Baltimore Longitudinal Study of Aging (BLSA).

Inclusion Criteria:

Men in the Baltimore Longitudinal Study of Aging (BLSA).

Exclusion Criteria:

- Had completed fewer than 4 days of a 7-day diet record for greater than 1 biennial visit
- Born after 1929 or age greater than 80 years at the first dietary record
- History of angina pectoris or myocardial infarction at baseline

Description of Study Protocol:

Recruitment

The BLSA began in 1958 and was designed to study normal human aging and precursors to disease and death. The current analysis includes a subset of 501 BLSA participants that met the inclusion criteria.

Design: Prospective Cohort Study

Men recruited for this prospective cohort completed a biennial visit which included a 7 day diet record. BLSA participants were trained to record their food intake by dietitians during their

examination visit and ambiguous or incomplete records were clarified by telephone interview. Vital status was followed for all participants and cause of death was determined by death certificate, hospital and physician records and autopsy data as available.

Blinding used (if applicable): No blinding was used.

Intervention (if applicable): No intervention was initiated.

Statistical Analysis

- Cox proportional hazards analysis was used to estimate risk of total and CHD mortality associated with dietary factors.
- Unpaired t tests and \dot{X}^2 analysis compared characteristics in survivors with men who died of any cause and with those who died of CHD.

Data Collection Summary:

Timing of Measurements

Dietary data were collected by 7-day diet record during 4 time periods: 1961-1965; 1968-1975; 1984-1991 and 1993-present time. Participants completed diet records at biennial visits. In this specific analysis, BLSA participants completed records for 4-49 days (mean = 19 days) at 1-7 visits over a mean follow-up of 18 years. Dietary records collected <2 years before death or subsequent development of clinical CHD were excluded due to the possibility diet may be affected by major illness.

Dependent Variables

- All cause mortality
- CHD mortality
- Diagnosis of clinical CHD

Independent Variables

- Intake of fruits and vegetables by serving
- Intake of saturated fat by gram
- Intake of micronutrients
- Intake of fiber

Control Variables

- Age at first visit
- BMI
- Energy intake
- Physical activity score
- Smoking status
- Alcohol use
- Vitamin supplement use

Description of Actual Data Sample:

Initial N: 501 men

Attrition (final N): All subjects included in the final analysis

Age: Born before 1929 and ≤80 years of age at the time of first diet record

Ethnicity: Not reported

Other relevant demographics: Demographics not reported in this paper but the authors did note that participants in the BLSA were not a random sample and are predominantly white men of relatively high socioeconomic status

Anthropometrics Significant differences were observed at baseline between survivors and CHD deaths in age at baseline (participants who died of CHD were slightly older at baseline) and smoking status.

Location: Baltimore, Maryland, United States

Summary of Results:

Key Findings:

- After adjustment for covariates, each serving of fruits and vegetables was associated with a 6% reduction in risk for total mortality (P<0.05) and a 21% reduction in CHD death (P<0.01)
- When examines separately, intake of fruit was associated inversely with total mortality (P<0.05) and intake of vegetables was inversely associated with CHD mortality (P<0.01) with a risk reduction of 40% per serving
- Each gram of saturated fat intake was associated with a 7% increased risk of CHD death (P<0.001)
- The inclusion of both saturated fat and fruit and vegetable intake into a model attenuated most of the associations with mortality; however intake of total fruits and vegetables and vegetables alone remained significantly protective against CHD mortality (P<0.05 and P<0.01, respectively). Saturated fat also remained significantly associated with CHD mortality after adjustment (P<0.05)
- A 50% reduction in CHD mortality per 100 mg of magnesium intake was found after adjustment for covariates and saturated fat (p<0.001)
- β -carotene showed a 10% reduction in risk for CHD mortality per mg (P<0.05)
- Dietary fiber showed a 6% reduction in risk for CHD mortality per gram (P<0.05)
- When examined together, participants consuming ≥5 servings of fruits and vegetables per day and <12% of energy intake came from saturated fat were 31% less likely to die of any cause (P<0.05) and 76% less likely to die from CHD (P<0.001)

Author Conclusion:

In conclusion, the results of this study support earlier observations that dietary intakes low in saturated fat or high in fruits and vegetables each offer protection against CHD mortality. In addition, however, our data suggest that the combination of both high fruits and vegetables with relatively low saturated fat intake offers greater protection against both total and CHD mortality than either practice alone.

Reviewer Comments:

Limitations noted by the authors:

- As in any long term study, one of the limitations is changes made to the methodology over the years
- Because men entered the study over a 34-year period, the effects of secular trends in dietary habits were difficult to separate from those of diet per se
- The current analysis was limited to men because women were not recruited into the BLSA until 1978

While the authors noted this limitation in their discussion of findings, it is important to note that this cohort was made up of only men and little demographic information was provided in this particular paper (although it may have been published elsewhere). Therefore, it is difficult to extrapolate the findings of this cohort study to the population as a whole.

It is unclear in reading the paper whether or not the investigators were blinded to outcome when conducting biennial visits with the participants, including collecting a diet history.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

- 1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)
- 2. Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?
- 3. Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?
- 4. Is the intervention or procedure feasible? (NA for some epidemiological studies)

Validity Questions

2.

1. Was the research question clearly stated? 1.1. Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified? 1.2. Was (were) the outcome(s) [dependent variable(s)] clearly indicated? 1.3. Were the target population and setting specified? Yes Yes

Was the selection of study subjects/patients free from bias?

	2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
	2.2.	Were criteria applied equally to all study groups?	Yes
	2.3.	Were health, demographics, and other characteristics of subjects described?	No
	2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	Were study	groups comparable?	Yes
	3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
	3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
	3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
	3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
	3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	Yes
	3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method	d of handling withdrawals described?	Yes
	4.1.	Were follow-up methods described and the same for all groups?	Yes
	4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	N/A
	4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
	4.4.	Were reasons for withdrawals similar across groups?	N/A
	4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blindir	ng used to prevent introduction of bias?	Yes

	5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
	5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
	5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	Yes
	5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
	5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.		vention/therapeutic regimens/exposure factor or procedure and rison(s) described in detail? Were interveningfactors described?	Yes
	6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
	6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
	6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
	6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
	6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
	6.6.	Were extra or unplanned treatments described?	N/A
	6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
	6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outco	mes clearly defined and the measurements valid and reliable?	Yes
	7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
	7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
	7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
	7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
	7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
	7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes

	7.7.	Were the measurements conducted consistently across groups?	Yes		
8.	Was the statistical analysis appropriate for the study design and type of outcome indicators?				
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes		
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes		
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes		
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A		
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes		
	8.6.	Was clinical significance as well as statistical significance reported?	Yes		
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	No		
9.	Are conclusions supported by results with biases and limitations taken into consideration?				
	9.1.	Is there a discussion of findings?	Yes		
	9.2.	Are biases and study limitations identified and discussed?	Yes		
10.	Is bias due t	to study's funding or sponsorship unlikely?	Yes		
	10.1.	Were sources of funding and investigators' affiliations described?	Yes		
	10.2.	Was the study free from apparent conflict of interest?	Yes		

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